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USSN: 09/756,690
Atty. Docket No.: 249/124US-UTL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kolterman, Orville G., et al.

Appln. No.: 09/756,690

Filed: 9 Jan 2001

For: *Use of Exendins and Agonists Thereof
for Modulation of Triglyceride Levels
and Treatment of Dyslipidemia*

Art Unit: 1646

Examiner: JIANG, Dong

Atty. Docket: 249/124US-UTL

Confirm. No.: 4666

United States Patent and Trademark Office
Commissioner for Patents
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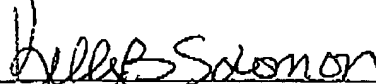
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<u>Documents(s)</u>	<u>No. of Pages</u>
Applicants' Statement of the Substance of the Interview of March 1, 2007	2
<i>Facsimile Cover Sheet</i>	1
Total Pages	2

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Kelly B. Solomon

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**APPLICANTS' STATEMENT OF THE SUBSTANCE OF
THE INTERVIEW OF MARCH 1, 2007**United States Patent and Trademark Office
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In response to the Interview Summary mailed March 2, 2007, Applicants respectfully submit the following "Statement of the Substance of the Interview of March 1, 2007."

Applicants thank the Examiner and Supervisory Examiner for the opportunity to discuss this application on March 1, 2007.

Applicants requested the interview in order to discuss the Office Action mailed December 14, 2006 (hereafter, the "New Office Action"). The New Office Action was mailed after a Notice of Panel Decision from Pre-Appeal Brief Review¹ was sent to Applicants indicating that the "rejection [in the previous office action] is withdrawn and a new Office Action will be mailed." However, the rejection was not withdrawn and the New Office Action did not appear to be substantially different from the office action previously mailed July 26, 2006 ("Previous Office Action"). At the conclusion of the Interview, it was agreed that the New Office Action was not substantially different from the Previous Office Action and Applicants indicated that they would consider filing an Appeal Brief.

Applicants provide the following comments with respect to the substance of the interview as summarized by the Examiner on the Interview Summary form.

¹ The Conference was held in response to Applicants' Pre-Appeal Brief Request filed August 16, 2006, which in turn was filed in response to the office action mailed July 26, 2006.

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At the interview, in addition to the references identified by the Examiner on the Interview Summary Form², the reference provided with Applicants' Response of June 15, 2006 and identified as Exhibit 1³ (the "Exhibit 1 reference") was discussed. As discussed at the interview, the Exhibit 1 reference demonstrates that drugs that lower plasma lipids do not necessarily lower triglycerides.

In the Examiner's summary of the substance of the interview, the Examiner makes statements characterizing the Beeley and Karpe references. Applicants respectfully disagree with the conclusions drawn by the Examiner and will address these conclusions in a future response. However, Applicants do wish to provide initial comments regarding statements made with respect to the Beeley reference. At the interview, the Examiner characterized Beeley as disclosing lipid lowering and made the statement that the major components of plasma lipids include cholesterol and triglycerides. The Examiner did not indicate that Beeley disclosed lowering triglycerides and cholesterol, as suggested by the Interview Summary.⁴

At least because Beeley does not disclose that exendin lowers triglyceride levels and because the triglyceride-lowering effect of any lipid-lowering compound is unpredictable (as demonstrated by the Exhibit 1 reference), Applicants respectfully maintain that neither Beeley nor Karpe, either alone or in combination, teach or suggest the claimed invention.

Respectfully submitted,
AMYLIN PHARMACEUTICALS, INC.

Dated: 27-Mar-07

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²Beeley, et al. (WO 98/30231) ("Beeley"), and Karpe et al. (Metabolism, 1999, 48: 301-307) ("Karpe")

³"Management of Dyslipidemia in Adults with Diabetes," *American Diabetes Association*, published in *Diabetes Care*, Volume 26, Supplement 1, S83-S86, January 2003

⁴The Examiner's Interview Summary states: "The examiner indicates that, besides teaching lowering plasma lipid (triglyceride and cholesterol) with exendin, Beeley also teaches using the same method for reducing cardiac risk, which would include the patient population taught in the Karpe reference."